

Congress Likely to Rein In 340B Drug Discount Program

The HRSA's Draft Guidance and a Proposed Rule Give Legislators an Opening

Stephen Barlas

Congress appears to be considering reining in a federal program that lets safety-net hospitals and community clinics use outpatient prescription sales to generate revenue. Repeated negative reports from federal watchdog agencies depict the 340B drug program as running off the rails for numerous reasons. The Health Resources and Services Administration (HRSA), the agency of the Department of Health and Human Services (HHS) that supervises the program, says it does not have the legal authority to provide the kind of oversight that is required. As of February 28, 2015, 11,180 providers were participating in the 340B program, according to HHS.¹ Hospitals buy 78% of the drugs purchased by those providers.

The HRSA Office of Pharmacy Affairs (OPA), which runs the 340B program, published a long-awaited "omnibus" draft guidance in late August² ostensibly clarifying some key issues that the Government Accountability Office (GAO) and the HHS Office of the Inspector General (OIG) have highlighted as undermining program integrity. But guidance is not enforceable.

"Rulemaking allows us to be more specific about our regulations and gives us stronger enforcement ability," states Diana Espinosa, HRSA Deputy Administrator. However, a 2014 federal court decision severely limited the OPA's rulemaking authority, a situation only Congress can correct.

The omnibus draft guidance hit the street at about the same time that 340B players were commenting on a proposed rule from the HRSA having to do with the prices drug companies can charge eligible hospital patients.³ The omnibus draft guidance would limit the patients who would be eligible for discounted drugs. These latest events give Congress, which has long ignored the 340B program, a chance to legislate, taking into account complaints about the draft guidance and proposed rule and giving the OPA a stronger legal footing that can be translated into enforceable regulations.

Stephanie Silverman, spokeswoman for the Alliance for Integrity and Reform of 340B, a group composed of drug companies, pharmacy benefit managers (PBMs), and some patient groups, points out that there was bipartisan support for 340B reform legislation to be included in the 21st Century Cures bill the House passed in July by a vote of 344–77. But a 340B amendment came up late in the game, and legislators dropped it out of fear that stakeholders had not had enough time to vet the language.

Now that the draft guidance is out, "we'll see where the holes are, and any legislation will be faster-moving," Silverman states. "There is clearly bipartisan appetite for moving legislation."

Josh Trent, a staffer at the House Energy and Commerce Committee, which held oversight hearings in March 2015, says he cannot comment on whether 340B remedial legislation is imminent. But the House has approved a new 0.1% fee on participants that is expected to generate \$7.5 million in fiscal year 2017 to be used for program integrity (that is, additional audits). This would be added to an annual budget that in fiscal 2015 amounted to about \$10 million.



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Complaints About 340B

About one-third of the hospitals in the country and a large number of federally funded health clinics use the 340B program to generate revenue, in some cases millions of dollars, by selling discounted prescription drugs at outpatient clinics. Hospitals and clinics love the program. Pharmaceutical manufacturers, PBMs, and others hate it. John J. Castellani, President and CEO of Pharmaceutical Research and Manufacturers of America, says:

Current hospital qualification criteria is misaligned with Congress' goal of supporting vulnerable patient access to prescription medicines. We owe it to these patients to ensure that the program remains sustainable in the future and, as such, it is critical to revise the eligibility criteria for hospitals and improve accountability and oversight.

The push by drug manufacturers to convince Congress to reform the 340B program gained support in June from a newly released GAO report.⁴ The GAO looked at a sample of 340B hospitals and found they were billing Medicare for higher drug costs under Part B than non-340B hospitals. Part B drugs are typically provided in a physician's office; a considerable percentage of those drugs are oncology medicines. "This indicates that, on average, beneficiaries at 340B disproportionate-share hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals in GAO's analysis," the GAO said.

Hospital groups disputed the GAO's methodology. Bruce Siegel, MD, CEO of America's Essential Hospitals (a trade group for safety-net hospitals), said in a statement: "We're surprised not only by the lack of evidence and data for GAO's conclusions and recommendations, but also by its suggestion that physicians in our nation's essential hospitals would ignore patient needs to enrich hospitals."

For their part, hospitals have complained about manufacturers overcharging and refusing to provide pricing information required by the 2010 Patient Protection and Affordable Care Act (PPACA). One of its provisions mandated that manufacturers report 340B prices to the HHS, which would make those prices public. That has not happened. HRSA's Espinosa says the new pricing system will be operational in late 2015.

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340B Program Details

Congress established the 340B program in 1992. To qualify to sell discounted 340B pharmaceuticals, hospitals and clinics, called “covered entities” in the program’s argot, must serve a large number of uninsured patients. The qualification standard relies on an indirect measure of the percentage of hospital patients covered by Medicaid. Covered entities include safety-net hospitals (referred to as disproportionate-share hospitals) owned or operated by state or local governments, as well as federal grantees such as federally qualified health centers (FQHCs), FQHC look-alikes, family planning clinics, state-operated AIDS drug-assistance programs, Ryan White CARE Act grantees, sexually transmitted disease clinics, and others as identified in the Public Health Service Act.

Drug companies *must* sell their medicines to 340B outpatient pharmacies at discounts of 25% to 50% *if* they want to sell to state Medicaid programs. The 340B cost for a drug paid by covered entities—sometimes referred to as the 340B ceiling price—is based on a statutory formula and represents the highest price a drug manufacturer may charge covered entities. It is based on the price companies charge Medicaid programs for that drug. Manufacturers are permitted to audit covered entities’ records if they suspect product diversion or multiple discounts are taking place. Occasionally, the formula results in a negative price for a 340B drug. In these cases, HRSA has instructed manufacturers to set the price for that drug at a penny for that quarter—a directive known as HRSA’s penny pricing policy.

The covered entities make their revenue by encouraging qualified patients—and the definition of *patient* is among the rubs—with commercial insurance to use those 340B pharmacies. There is no family income cap on patient eligibility; millionaires with or without health insurance and the destitute are both eligible to visit 340B pharmacies. The hospital or clinic then bills the insurance company of insured patients for the full price of the drug, and pockets the difference between that price and the discounted price.

Some programs provide 340B drugs to prison inmates, a fact that appeared to take one House subcommittee chairman by surprise. David Bowman, an HRSA spokesman, explains that under current law, correctional facilities are not 340B covered entities eligible to purchase drugs under the 340B Drug Pricing Program. However, these facilities and their patients may be eligible for the 340B program under certain circumstances:

- In the case of hospitals, if the clinic at which the covered entity provides health care services to incarcerated persons is an integral part of the hospital and the clinic is listed as reimbursable on the entity’s most recently filed Medicare cost report, then the clinic may be eligible.
- For other covered entities, if the clinic where the covered entity provides health care services to incarcerated persons is within the scope of its grant, then the clinic may be eligible.

“There are a very small number of 340B covered entities, 29, that currently operate sites within a prison, jail, or detention center,” Bowman says.

Criticism of the Program

The OIG has evaluated and audited the program for more than a decade, focusing on the impact of 340B on federal Medicaid and Medicare spending. From the start, the OIG found numerous deficiencies in HRSA’s oversight of the program.¹ These deficiencies included inaccurate information about which providers were eligible for the discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. In the latter case, confidentiality protections prevented HRSA from sharing the ceiling prices with the 340B providers, leaving them in the dark as to whether they were being charged correctly by drug manufacturers. The PPACA provision was supposed to eliminate that problem.

The lack of price transparency can result in the federal government and states paying more for drugs for Medicaid patients than otherwise necessary. Medicaid patients are eligible to receive 340B drugs. States pay for 340B-purchased drugs when 340B providers dispense them to Medicaid patients. Many states have established Medicaid policies to pay for 340B-purchased drugs at 340B providers’ actual acquisition cost; these policies ensure that Medicaid realizes savings from the discounted 340B prices. However, OIG found that without access to 340B ceiling prices, states are unable to implement automated, prepayment edits to enforce these policies. A decade ago, the OIG found that 14% of prices charged by drug companies were too high, resulting in overcharges of \$3.9 million a month.⁵ That report has never been updated.

Apart from the impact of opaque and excess pricing on Medicaid expenditures, the increasing number of contract pharmacies used by covered entities—first allowed by HRSA in 2010—has made it difficult for state Medicaid programs to determine which 340B claims are actually eligible for reimbursement at the higher rate. A corollary to this problem is that confusion over claims can result in drug manufacturers having to offer discounts for the same patient and drug twice. Duplicate discounts occur when drug manufacturers pay state Medicaid agencies rebates under the Medicaid drug rebate program on drugs they sold at the already-discounted 340B price.

The contract pharmacy expansion the OPA allowed in 2010 also complicates a pharmacy’s ability to know whether a particular customer is eligible for 340B pricing. The pre-2010 guidance specifies that an individual is an eligible patient only if he or she has an established relationship with the 340B provider, he or she receives health care services from the 340B provider, and those services are consistent with the service or range of services for which federal funding is being granted. That determination was much easier to make prior to 2010, when eligible patients could obtain 340B drugs only from the hospital’s inpatient pharmacy. Now covered entities send their ostensibly eligible patients to retail pharmacies, which have a much more difficult time determining whether their customer is 340B-eligible. Most do that after the fact, often matching information from the 340B providers, such as patient and prescriber lists, to their dispensing data. “Depending on the interpretation of HRSA’s patient definition, some 340B provider eligibility determinations would be considered diversion and others would not,” says Ann Maxwell, OIG’s Assistant Inspector General for Evaluation and Inspections.

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The GAO has focused more on the impact of 340B idiosyncrasies on Medicare spending. The GAO's latest report in June reported higher spending by Medicare for drugs sold to patients at 340B hospitals than at non-340B hospitals.⁴ The Centers for Medicare and Medicaid Services, which administers the Medicare program, uses a statutorily defined formula to pay hospitals for drugs at set rates regardless of hospitals' costs for acquiring the drugs. The report states:

Therefore, there is a financial incentive at hospitals participating in the 340B program to prescribe more drugs or more expensive drugs to Medicare beneficiaries. Unnecessary spending has negative implications, not just for the Medicare program, but for Medicare beneficiaries as well, who would be financially liable for larger copayments as a result of receiving more drugs or more expensive drugs. In addition, this raises potential concerns about the appropriateness of the health care provided to these beneficiaries.

"The federal government doesn't know where the dollars are going," says U.S. Representative Renee Ellmers (R-North Carolina). She cites a study by the IMS Institute for Healthcare Informatics that found the cost of 10 chemotherapy infusion drugs was 189% higher at the 340B hospitals than at private physicians' offices.⁵

The HRSA in many cases does not have the legal authority to respond to these programmatic weaknesses. In May 2014, a ruling by the U.S. District Court for the District of Columbia said HRSA could issue legally binding, enforceable regulations in only three areas, which did not include the definition of a patient, participation of contract pharmacies, and hospital participation in the program. U.S. Representative Fred Upton (R-Michigan), Chairman of the House Energy and Commerce Committee, says HRSA's inability to issue regulations is "hampering the ability of the agency to manage the program as we'd like."

Congress Becomes More Attentive to 340B

The GAO and OIG reports, with their negative implications for federal health care spending, along with the federal court decision, have apparently forced Congress to revisit a program it has long ignored. Moreover, the PPACA's support for expansion of state Medicaid programs—28 states have done that so far—means that far fewer poor individuals are uninsured and that uncompensated care at hospitals is falling sharply as a result.

At hearings in March—the first 340B oversight hearings the committee had held since 2005—U.S. Representative Joe Pitts (R-Pennsylvania), Chairman of the House Energy and Commerce health subcommittee, asked Debbie Draper, Director of Health Care at the GAO, whether the PPACA's Medicaid expansion means the access of hospitals to the 340B program should be circumscribed. Her response: "That is an interesting question, and difficult to answer because much has changed in the health care landscape the last few years. The bigger question is, what is the intent of 340B? There is lack of clarity around that."

HRSA's Espinosa agrees. "The law doesn't specify how the savings hospitals earn from 340B should be used," she says.

Aside from the kind of technical, definitional, and accounting

shortcomings plaguing the program, there is also the matter of the program's objective. When Congress established the 340B program in 1992, the rationale was that hospitals and community clinics serving low-income patients needed a way to stretch scarce resources, allowing them to reach more eligible patients and provide more comprehensive services. Rather than set up a grant program using federal dollars, Congress forced drug manufacturers to sell medications at a discounted price and allowed hospitals to raise revenue via the differential between the discounted price and the price they billed insurance companies when an insured person purchased those drugs. It was not clear, however, which patients were eligible to purchase the discounted drugs, and whether the program's purpose was to help the poor and uninsured afford expensive drugs or to allow hospitals in poorer communities to fund their operations.

The GAO's Maxwell, when asked by Pitts about the impact of the reduction in uncompensated hospital care, replied, "The bigger problem is the intent of the 340B program." Echoing Draper, she added: "There is a lack of clarity on that."

This lack of clarity looms larger every year as the program expands almost geometrically, with the result that both hospitals, for their reasons, and drug manufacturers, for their reasons, complain louder and louder about unqualified patients using the program and about rogue drug company pricing. In 2010, Congress in the PPACA allowed states to expand the number of Medicaid patients they serve, which had the contradictory effect of first boosting the number of hospitals that are eligible (because eligibility is tied loosely to a hospital's Medicaid population) and simultaneously reducing uncompensated hospital care.

The PPACA also expanded the kinds of health care settings that could qualify for the 340B program to: 1) certain children's and free-standing cancer hospitals excluded from the Medicare prospective payment system; 2) critical-access hospitals; and 3) certain rural referral centers and sole community hospitals. In 2011, the number of hospitals participating in the program was nearly three times what it was in 2005, and the number of these organizations, including their affiliated sites, was close to four times what it was in 2005, according to the GAO. Hospitals' participation in the 340B program has grown faster than that of federal grantees; the number of participants increased almost threefold from 2005 to 2011. Disproportionate-share hospitals alone represent about 75% of all 340B drug purchases.

In 2010, HRSA pumped up the program by allowing hospitals to sell discounted drugs from outpatient pharmacies located off a hospital's main grounds. Before, sales were only allowed where a pharmacy was located next to an inpatient facility.

HRSA's Response

It wouldn't be fair to blame the OPA entirely, or even mostly, for the shortcomings of the 340B program. Congress provided some weak underpinnings initially and then piled more program complexities on top of that shaky foundation. Congressional appropriations for the program have been anemic, particularly until 2009, when the program's budget was \$1.5 million. It has risen to \$10 million a year, but that still makes it one of the worst-funded federal agencies with enforcement responsibilities. The program's visibility is almost nil. The OPA, whose

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sole responsibility is the 340B program, isn't even listed with the other "offices" on the HRSA organizational chart.

Additional congressional appropriations over the past few years have allowed the OPA to begin auditing—mostly hospitals and not many drug manufacturers. The OPA has conducted about 50 to 100 audits a year since fiscal 2011, according to its website. Looking through the summaries of the most recent audits in fiscal 2015, the vast majority of hospitals that were audited either terminated their contract pharmacies or repaid manufacturers because of diversion of 340B drugs to unqualified patients.

Some of that diversion will go away based on the proposed restrictions in the draft guidance on patients eligible for 340B drugs. Hospital groups aren't happy about the new restrictions. 340B Health, a trade group representing safety-net hospitals who take advantage of the program, says it hopes "safety-net health care providers will not find themselves limited in their ability to meet their mission to treat the underserved." So there will be pushback, undoubtedly, against the proposed definitional changes to "patient." And in any case, whatever the language in the final guidance, it will still just be guidance. The HHS won't be able to enforce it unless Congress encodes the changes into law.

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